REMARKS

I. Status Summary

This Amendment is filed in response to the Examiner's Answer dated February 3, 2011, which contained new grounds of rejection for most of the pending claims. Applicant kindly requests that prosecution be reopened, and the claims amended as enclosed herewith.

Upon entry of this Amendment, claims 1, 3-10, 12-13, 15, 17 and 20 are pending in the application.

II. Claim Rejections

Claims 1, 2, 7, 9, 13, 16 are rejected over Dracker (US 5,356,373) under 35 USC 102(b). Claims 3-6 are rejected under 35 USC 103(a) for being obvious over Dracker in view of Deverre (US 7,131,958). Claim 8 is rejected under 35 USC 103(a) for being obvious over Dracker in view of Darling (US 6,213,986). Claim 10 is rejected under 35 USC 103(a) for being obvious over Dracker in view Van Der Heiden (US 5,879,318). Claims 12, 15, 17 & 19 are rejected under 35 USC 103(a) for being obvious over Dracker in view of Seddon (US 6,024,731).

A. Dracker fails to disclose each and every feature of claims 1, 7, 9 and 13 under 35 U.S.C. § 102(b)

Claim 1 includes "a vacuum bottle in fluid connection with said at least one needle via said at least one tube, for sucking and collecting placental blood directly therein,

wherein the vacuum bottle is the vacuum source for the placental-blood extraction device".

Appellant respectfully submits that Dracker fails to disclose the vacuum bottle of the claimed invention.

Dracker discloses a method and apparatus for storing umbilical blood. A flexible collection bag is attached to a needle via a tube (col. 6, lines 28-32). The collection bag is disposed inside a rigid hollow box. The hollow box has an external vacuum source which provides suction to the interior of the box, via a vacuum fitting (pipe fitting) on a bottom panel of the box (col. 3, lines 17-20). This suction is provided in the box, but to the exterior of the flexible bag. When the external vacuum source provides the vacuum suction to the interior of the box, a vacuum pressure is applied to the flexible collection bag disposed in the box, thereby allowing suction through the needle to facilitate removal of blood from the umbilical cord (col. 4, lines 45-53).

As noted, the bag is placed inside the rigid box (col. 5, lines 47-50) having the vacuum fitting (col. 6, lines 13-17). Vacuum pressure is applied inside the box by the external vacuum source via the vacuum fitting on the box panel (col. 6, line 17). The vacuum pressure inside the box causes expansion of the flexible bag inside the box, and thus suction through the needle (col. 4, lines 45-53). The drawing effect is achieved by the vacuum created within the box (col. 3, lines 51-52). That is, the vacuum is applied from a separate source other than the flexible collection bag; the collection bag merely responds to the vacuum created in the box which is external to the bag.

The Examiner broadly interprets the rigid box in Dracker to be a bottle and since it contains the collection bag, the examiner further considers it to be a collection vessel (see Examiner's Answer, page 4).

However, the box is not a bottle.

As clearly shown in FIG. 1, and understood by one of ordinary skill in the art, a bottle is an elongated rigid structure having a mouth. *See also*, Merriam-Webster's Online Dictionary

(bottle (noun): a rigid or semi-rigid container typically of glass or plastic having a comparatively narrow neck or mouth and usually no handle).

One of ordinary skill in the art would not consider a box to be a bottle. A comparison of FIG. 2 of Dracker to FIG. 1 of the pending application illustrates the structural distinction. *See also*, Merriam-Webster's Online Dictionary (box (noun): a rigid typically rectangular container with or without a cover).

As such, the rectangular box in Dracker is not a bottle.

In addition, the bag is not a bottle. The flexible bag in Dracker is purposefully flexible and not a rigid container.

In view of the foregoing, claim 1 is not anticipated by Dracker because Dracker fails to disclose a "bottle".

Still further, the bottle in claim 1 is a vacuum bottle. A vacuum bottle is understood by one of ordinary skill in the art to provide a vacuum source. The pending specification provides an example of a vacuum bottle, namely, a Redon-type vacuum bottle which is illustrated in FIG. 1 (see page 6 of specification).

In direct comparison, neither the box or the bag in Dracker is a vacuum source by itself. Instead, the vacuum source is external to both the box and bag.

Thus, Dracker fails to disclose a vacuum bottle.

For at least the foregoing reasons, claim 1 is not anticipated by Dracker.

Moreover, claims 7 and 9 are patentable for at least the same reasons as claim 1, by virtue of their dependency therefrom.

Claim 13 includes "means for sucking and collecting placental-blood, in fluid connection with the needle via the tube".

Appellant respectfully submits that Dracker fails to disclose the means for sucking and collecting placental-blood of the claimed invention.

The means for sucking and collecting recited in claim 13 is to be given means plus function treatment under 35 U.S.C. § 112, sixth paragraph. The recited function is sucking and collecting. The corresponding structure is the element 30, shown in FIG. 1 and discussed on page 3 of the specification.

Dracker discloses a flexible collection bag is attached to a needle via a tube (col. 6, lines 28-32). The collection bag is disposed inside a rigid hollow box. The hollow box has an external vacuum source which provides suction to the interior of the box, via a vacuum fitting (pipe fitting) on a bottom panel of the box (col. 3, lines 17-20). This suction is provided in the box, but to the exterior of the flexible bag. When the external vacuum source provides the vacuum suction to the interior of the box, a vacuum pressure is applied to the flexible collection bag disposed in the box, thereby allowing suction through the needle to facilitate removal of blood from the umbilical cord (col. 4, lines 45-53).

As noted, the bag is placed inside the rigid box (col. 5, lines 47-50) having the vacuum fitting (col. 6, lines 13-17). Vacuum pressure is applied inside the box by the external vacuum source via the vacuum fitting on the box panel (col. 6, line 17). The vacuum pressure inside the box causes expansion of the flexible bag inside the box, and thus suction through the needle (col. 4, lines 45-53). The drawing effect is achieved by the vacuum created within the box (col. 3, lines 51-52). That is, the vacuum is applied from a separate source other than the flexible collection bag; the collection bag merely responds to the vacuum created in the box which is external to the bag.

The Dracker device could not provide any suction without the external vacuum source, and thus, this is a necessary element for the device in Dracker to function. That is, neither the bag nor the box is the vacuum source for the device.

Thus, Dracker requires at least the following elements: (1) a flexible bag connected to the needle, (2) a rigid box receiving the flexible bag and (3) a vacuum source to create a vacuum inside the box and outside the flexible bag receiving the blood.

This structure disclosed in Dracker for achieving the claimed function is not equivalent to the claimed means for sucking and collecting. Applicant provides a single container that sucks and collects the blood. There is no external vacuum source, the vacuum being inside the blood collection container because the vacuum bottle is the vacuum source.

The structure of the claimed invention is simpler, with less components compared to Dracker, and the operation is also much simpler and quicker in the claimed invention as compared to Dracker.

Indeed, the claimed invention requires opening of the package containing the blood collection device, piercing of the vein, and opening of the valve to open passage between the needle and the container.

On the other hand, Dracker's device requires opening of the package containing the blood collection device, connection of the box to a vacuum source, piercing of the vein, and opening of the vacuum source.

Dracker thus requires more steps and can be used only at the vicinity of an external vacuum source, whereas the invention is fully independent of such an external vacuum source, and can be used alone, anywhere, because the vacuum bottle is the collection vessel.

In view of the foregoing, Appellant respectfully submits that the three component structure formed by the flexible bag, the rigid box, and the external vacuum source of Dracker is

not equivalent to the single component system of the suction and collection means of the claimed invention which includes simply the vacuum bottle for providing the vacuum source and the collection vessel for the device.

As such, Appellant respectfully submits that Dracker fails to anticipate claim 13.

B. Claims 3-6 are not rendered obvious by the combination of Dracker and Deverre under 35 U.S.C. § 103(a)

Claims 3-6 depend from claim 1. Because Dracker fails to disclose each and every structural component of claim 1, and because Deverre fails to cure the deficiencies of Dracker noted above with respect to claim 1, claims 3-6 are patentable at least by virtue of their dependency from claim 1.

C. Claim 8 is not rendered obvious by the combination of Dracker and Darling under 35 U.S.C. § 103(a)

Claim 8 depends from claim 1. Because Dracker fails to anticipate claim 1, and because Darling fails to cure the deficiencies noted above with respect to claim 1, claim 8 is patentable at least by virtue of its dependency from amended claim 1.

D. Claim 10 is not rendered obvious by the combination of Dracker and Van der Heiden under 35 U.S.C. § 103(a)

Appellant respectfully submits that the combination of Dracker and Van Der Heiden fails to disclose the device assembled "in a single package" so as to be ready to use once the package is opened.

As noted above, Dracker requires the use of an external vacuum source. Van der Heiden is silent as to the vacuum source.

The combination of Dracker and Van der Heiden may disclose the concept of packaging the device in a sterile package, but it is not possible to package the Dracker device in a single package which is ready to use, because the vacuum source in Dracker is external to the rest of the device. Since Van der Heiden is silent with respect to a vacuum source, there is no teaching

or suggestion to modify Dracker to have its vacuum source provided internally with the rest of the device so as to be capable of being in a single package.

Accordingly, claim 10 is patentable over the combination of Dracker and Van der Heiden for these reasons in addition to the reasons discussed above with respect to claim 1.

E. Claims 12, 15, 17 and 19 are not rendered obvious by the combination of Dracker and Seddon under 35 U.S.C. § 103(a)

The rejection asserts that it would have been obvious to modify the box in Dracker with the bottle in Seddon "for the purpose of allowing the practitioner to gauge how much suction is left in the collection vessel and not needing a separate suction source at the time of blood extraction." (See Office Action at page 8.)

Claims 12 and 15 include a Redon bottle. Applicant respectfully submits that there is no predictability that the bottle disclosed in Seddon would provide a sufficient vacuum for a placental blood collection device.

A Redon-type bottle had never been used for placental blood extraction in the prior art. Because the Redon-type bottle extracts fluid differently from the vacuum device in Dracker, this is not a simple manner of substitution. A Redon-type device is used for wound drainage in Seddon, because the collection of wound fluids is a slow process which often takes place during surgery or post-surgery over several days. The suction is performed slowly since the fluid builds up in the wound slowly.

This type of extraction is very different from the type of extraction in Dracker. Dracker and the claimed invention use a needle to pierce a vein in order to collect the blood. This is completely different from the device in Seddon which slowly drains fluid from a wound site via a tube without a needle. The type of device in Seddon does not pierce a vein. Thus, there is no predictability that a Redon-type bottle would be useful in a blood collection device which must collect fluid quickly, in a matter of minutes to prevent coagulation of the blood.

That is, Dracker collects the blood in under two minutes (col. 7, lines 25-30). One would not have thought to have substituted the quick suction box device in Dracker with the slow vacuum bottle in Seddon.

As such, the rationale to substitute the Dracker box with the Seddon bottle "for the purpose of allowing the practitioner to gauge how much suction is left in the collection vessel and not needing a separate suction source at the time of blood extraction" is misplaced and one of ordinary skill in the art would not have made this substitution.

In addition, evidence showing secondary considerations is a showing of non-obviousness. *Graham v. John Deere Col.,* 383 U.S. 1, 17 (1966). The failure of others to invent is relevant to the obviousness inquiry as such a secondary consideration. *Ryko Manufacturing co., v. Nu-star inc.,* 950 F.2d 714 (Fed. Cir. 1991).

Redon bottles have been used for wound drainage for many years. However, Redon bottles have never been used for placental blood collection. Because the particular combination of well known elements have never been proposed for placental blood collection, this failure to propose the invention is a strong indication that the combination of elements is inventive, and Appellant has discovered a novel and nonobvious use for a Redon-type bottle.

Heretofore, several systems have been known for collecting placental blood, and each of the prior art systems require a specific application of a vacuum source to provide suction. While the use of a Redon-type vacuum bottle is well known for the slow collection of wound secretions, a Redon-type bottle has never been considered in connection with collecting blood in a vein. The use of a Redon-type bottle has been limited to slow wound drainage, over several days.

Moreover, the collection bag disclosed in Dracker is intended to store the placental blood; in contrast, the bottle in Seddon is intended to be thrown away. There is no evidence that Seddon's bottle would be viable for blood storage.

For at least the foregoing reasons, Appellant respectfully submits that it would not have been obvious to modify the box in Dracker with the Redon bottle of Seddon "for the purpose of allowing the practitioner to gauge how much suction is left in the collection vessel and not needing a separate suction source at the time of blood extraction" because the use of a Redon-type bottle was not a predictable variation for an external vacuum source system. Moreover, the fact that the well known Redon-type bottle had been known in the medical field for many years but never used for venal blood collection before Applicant's invention is further evidence of nonobviousness.

In addition, claims 12 and 15 are patentable for at least the same reasons as claims 1 and 13, by virtue of their dependency therefrom.

Appellant submits that method claims 17 and 20 are not rendered obvious by the combination of Dracker and Seddon.

A method of placental blood extraction using a vacuum bottle is novel and nonobvious.

Heretofore, a vacuum bottle has not been used for venal blood extraction.

The rejection asserts that it would have been obvious to modify the box in Dracker with the bottle in Seddon "for the purpose of allowing the practitioner to gauge how much suction is left in the collection vessel and not needing a separate suction source at the time of blood extraction." (See Office Action at page 8.)

However, there is no predictability that the bottle disclosed in Seddon would provide a sufficient vacuum for a placental blood collection device. A pre-charged vacuum flask such as that disclosed in Seddon had never been used for placental blood extraction in the prior art.

Because the bottle extracts fluid differently from the vacuum device in Dracker, this is not a simple manner of substitution. The bottle used for wound drainage in Seddon collects wound fluids slowly during surgery or post-surgery over several days. The suction is performed slowly since the fluid builds up in the wound slowly.

This type of extraction is very different from extraction from a vein.

There is no predictability that the wound drainage bottle in Seddon would be useful in a blood collection device which must collect fluid quickly in a matter of minutes to prevent coagulation of the blood.

That is, since Dracker collects the blood in under two minutes (col. 7, lines 25-30), one would not have thought to have substituted the box device in Dracker with the slow vacuum bottle in Seddon.

As such, the rationale to substitute the Dracker box with the Seddon bottle "for the purpose of allowing the practitioner to gauge how much suction is left in the collection vessel and not needing a separate suction source at the time of blood extraction" is unsupported, appears to be based on hindsight, and one of ordinary skill in the art would not have made this substitution.

In addition, evidence showing secondary considerations is a showing of non-obviousness. *Graham v. John Deere Col.,* 383 U.S. 1, 17 (1966). The failure of others to invent is relevant to the obviousness inquiry as such a secondary consideration. *Ryko Manufacturing co., v. Nu-star inc.,* 950 F.2d 714 (Fed. Cir. 1991).

Redon bottles have been used for wound drainage for many years. However, Redon bottles have never been used in a method which involves piercing a vein for blood collection. Because the particular combination of well known elements have never been proposed for placental blood collection, this failure to propose the invention is a strong indication that the

combination of elements is inventive, and Applicant has discovered a novel and nonobvious method for using a Redon-type bottle.

For at least the foregoing reasons, claims 17 and 20 are not rendered obvious by Dracker and Seddon.

III. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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